

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA,

Indictment No.: 20 CR 160 (MKV)

v.

SETH FISHMAN, and
LISA GIANNELLI,

Defendants.

-----X

**DEFENDANTS' RESPONSE TO THE
GOVERNMENT'S MOTIONS *IN LIMINE***

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INTRODUCTION

Under the title “Relevant Facts,” the Government forgoes offering a procedural history, or a synopsis of the charges contained in the Indictment. Instead, it offers what amounts to an argument asserting the guilt of these defendants.

This kind of introduction to an *in limine* motion ignores the presumption of innocence and a defendant’s right to a trial at which he will be accorded due process of law. Among the constellation of rights which together provide due process, is the right to a trial in which evidentiary rulings will not be made by a Court that accepts the guilt of our clients as a forgone conclusion.

In lieu of a counter-argument, I will note that there are two caveats to our response to the Government’s *in limine* motions.

First, much of the evidence that the Government will seek to introduce against Dr. Fishman at trial was the subject of a series of proffer agreements. In 2009, the Government sought Dr. Fishman’s testimony in the trial of *United States v. David H. Brooks et al.*, 06CR550 (JS). Dr. Fishman was represented by counsel who appeared at the initial interview with the Government. In order to obtain his information regarding his dealings with the defendant, the parties entered into a proffer agreement on November 20, 2009. The agreement reflected the standard language then in use in the Eastern District of New York. Thus, paragraph 3 reads as follows:

Notwithstanding paragraph (2) above, the Office may use any statements made by Client: (A) to obtain leads to other evidence, which evidence may be used by the Office in any stage of a criminal prosecution (including but not limited to

detention, hearing, trial or sentencing), civil or administrative proceeding, (B) as substantive evidence to cross examine Client, should Client testify, and (C) as substantive evidence to rebut, directly or indirectly, any evidence offered or elicited or factual assertions made, by or on behalf of Client at any stage of a criminal prosecution (including but not limited to detention hearing, trial or sentencing).

Dr. Fishman's continued involvement as a potential witness against Brooks was secured only after the Assistant United States Attorney represented to Dr. Fishman that he was neither a subject nor a target of the Government's investigation.

Then, shortly after Dr. Fishman's arrest on the charges in the instant case, he engaged in a series of proffer sessions with the Government with the intention of securing a deferred prosecution agreement. These sessions took place on November 8, 2019, November 12, 2019 and February 11, 2020.

These interviews, likewise, were held pursuant to the terms of a limited immunity agreement. The agreement provided, in pertinent part:

(3) Notwithstanding (2) above: (A) the Government may use information derived directly or indirectly from the meeting for the purpose of obtaining leads to other evidence, which evidence may be used in any prosecution of Client by the Government; (B) in any prosecution brought against Client, the Government may use statements made by Client at the meeting and all evidence obtained directly or indirectly therefrom for the purpose of cross examination should Client testify; and (C) the Government may also use statements made by Client at the meeting to rebut any evidence or arguments offered by or on behalf of Client (including arguments made or issues raised *sua sponte* by the District Court) at any stage of the criminal prosecution (including bail, all phases of trial, sentencing) in any prosecution brought against Client.

To date, the Government has not made any showing that evidence elicited during these proffer sessions falls within one of those categories that result in the waiver of the immunity

granted by these provisions.¹ However, for the purpose of responding to these motions, defense counsel will refer to the evidence that may be introduced, should it be determined that the defendant seeks to present factual evidence and arguments.

Secondly, defense counsel is aware that during the course of the meetings conducted by his predecessor in the effort to secure for Dr. Fishman a deferred prosecution or non-prosecution agreement, arguments in favor of a lenient disposition of the pending charges were made by counsel. It appears that these arguments have impacted the Government's efforts to preclude, peremptorily, certain lines of defense.

And, while Ms. Giannelli never engaged in meetings with the Government, the Government has, likewise, made efforts to preclude her from asserting certain lines of defense.

We can assure the Court that the defendants do not intend to offer evidence or arguments speculating as to why other individuals engaged in activities similar to the charged conduct were not the subject of criminal prosecution. (Gov't Motion *in limine*, IV); that the defendants will not invoke an advice of counsel defense (*Id.* at VI); nor will the defendants offer a defense of public authority or entrapment by estoppel (*Id.* at VII).

However, it does not follow that any evidence which might otherwise be offered in support of one of those defenses, is rendered inadmissible at trial. To offer but one example, while the defendants will not seek a charge on the "advice of counsel" defense, each of them retains the right to elicit evidence, including evidence of consultation with counsel, to the extent that it is relevant to demonstrate a lack of intent to commit the crimes charged.

¹ Should the Government claim that the proffer statements are currently admissible, we would request written notice and an opportunity to brief the issue and to be heard.

With these considerations in mind, we will address the Government's arguments, in turn.

ARGUMENT

I. The Court Should Permit The Introduction Of Statements By The Defendants, Their Agents And Co-Conspirators When Offered For A “Non-Hearsay” Purpose (Gov’t MIL I And II)

The Government argues that it should be permitted to offer into evidence out of court statements made by the defendants and others in furtherance of the conspiracies charged against them in the Indictment. These statements would be offered as admissions, statements in furtherance of the conspiracy or as statements of agent and employees of the defendant while acting within the scope of an agency relationship. *See* Fed.R.Evid. Rule 801(d)(2)(A), (D), and (E).

The defendants have no objection to the introduction of such statements as a matter of principle. However, all such statements must still meet the test of relevance set forth in Fed.R.Evid. Rule 403. Statements offered as admissions by the defendant, or co-conspirator declarations, which are likely to inflame the jury, or confuse them as to the relevant issues, are still subject to objection by counsel and preclusion by the Court.

Moreover, the defendant takes issue with the blanket assertion that the Court should preclude the defendants from offering their own statements. The Government is right to assert that when the defendant seeks to introduce his own prior statement for the truth of the matter asserted, it is hearsay, and therefore not admissible. (Gov’t MIL at p.14). However, there are likely to be numerous instances in which the defendant may seek to introduce into evidence out of court statements of his own, or statements by an alleged co-conspirator or agent, for a non-hearsay purpose, such as to provide context or as evidence of the defendant's state of mind.

A conversation cited by the Government as evidence it will seek to elicit provides a useful example of an instance in which statements by the defendant, or others, can be admitted on the defense case. At page 37 of the Government's Motion *in limine*, it cites to the following statement by the Dr. Fishman, on a call with a foreign potential client intercepted on the defendant's cellular telephone, as evidence of his "intent as to [his use of his products] regardless of the jurisdiction in which the drug was administered:"

I design programs for people. So if you're somebody whose got a bunch of endurance horses and you know what you are doing and that's why I technically only work with trainers that have a certain amount of horses or more cuz it would make sense to do it. I design programs for people. I mostly work in regenerative peptides and I work in things that are not commercially available. [...] Every now and then people will ask me to make products because they want to go sell them to people who really don't know what's going on. Mostly, camel guys that are in the desert. I don't have to tell you how it is right [...] but I can meet with you [in Dubai]. You can explain to me your needs and wants and I can tell you how there's things that I made for other people that are not exclusive to them if you want your own exclusive stuff, I'll tell you how we go about doing it. The reason I say that certain people want exclusivity is because obviously if these horses are being tested, and they have something that someone else has and that person is irresponsible then it becomes a problem for them.

(Gov't MIL at pp.37-38).

At the outset, we note our objection to the Government's attempt to introduce evidence of foreign sales in order to have the jury draw inferences regarding the defendant's intent to defraud or mislead regulators and the betting public in the United States. As noted in IV of this Response, the defendant's foreign sales are subject to the export exemption to the adulteration and misbranding statutes. They require adherence to a regulatory regime that is entirely different from the one that prevails in the United States. Accordingly, such evidence is of marginal relevance and will result in substantial prejudice and the confusion of issues. *See Fed.R.Evid. Rule 403.*

The Government seeks to offer this statement on the basis that it “reflects Fishman’s overall intent in his drug design – to avoid testability while increasing performance.” (*Id.* at 38). However, the defendant’s assertion “I design programs for people,” is fully capable of another reading. Are these programs designed to improve the animal’s performance during a race; or, are they designed to promote the health and welfare of the animal and help it withstand the rigors of training?

Evidence designed to put this statement into context should be admissible. By the same token, evidence regarding the intent of the defendant’s “programs” is admissible as evidence of his state of mind.

Accordingly, this Court should not subscribe to the Government’s request for blanket preclusion of all statements by the defendant, his co-conspirators and agents, whether or not offered for truth of the matter asserted.

II. The Court Should Limit The Government’s Use Of Records From The Delaware State Division Of Professional Regulation Investigation Into Fishman And Giannelli (Gov’t MIL IX)

The Government notes that in or about January 2011, Dr. Fishman and Lisa Giannelli were the subject of an investigation by the State of Delaware, Division of Professional Regulation on the basis of a Complaint lodged by a veterinarian who claimed that a racehorse had been injected with one of Dr. Fishman’s drugs and had subsequently died. The Government seeks to admit: (1) the Complaint; (2) recorded interviews of Fishman and Giannelli in connection with that investigation; and (3) the defendants’ written response to the Complaint made through their shared counsel and adopted by each of the defendants through notarized attestations.

In the defendants' *in limine* Motions, counsel for Dr. Fishman argued that all of the evidence regarding this investigation should be precluded, citing Fed.R.Evid. Rule 403. Counsel noted that the Complaint contained the unproven allegation that Dr. Fishman was dispensing products without establishing the required Veterinarian-Caregiver-Patient-Relationship ("VCPR"). Further, investigators first reached the demonstrably false conclusion that Dr. Fishman did not maintain a license in the State of Delaware. Further, the owners and trainers of the racehorse refused to permit the animal to be subjected to a full autopsy, in all likelihood, because it would substantiate the suspicion of investigators that the cause of death was an inter-arterial injection of the product administered – rather than the content of the product itself. And, the investigation did not result in any sanction directed toward Dr. Fishman or Ms. Giannelli. Accordingly, counsel argued that the probative value of this evidence was substantially outweighed by the danger of unfair prejudice and confusion of the issues. *See* Fed.R.Evid. 403.

The Government asserts that it offers the evidence, not for the truth of the matters asserted, but (1) to establish Fishman and Giannelli's knowledge of the allegations in the Complaint; and (2) to demonstrate their intent to defraud and mislead that particular state drug regulator; as well as (3) to prove the defendant's knowledge that the Food Drug & Cosmetics Acts (FDCA) applies to the products at issue here.

First of all, there is no mention in the documents and testimony, that Dr. Fishman and Ms. Giannelli are being investigated for an alleged violation of the adulteration and misbranding statutes. Accordingly, the introduction of this evidence does not demonstrate the defendant's knowledge of the relevant portions of the FDCA.

Second, the Government's goal of using the evidence to demonstrate the defendant's knowledge of the allegations, and his intent to defraud, or mislead, can be achieved through the

introduction of redacted versions of the documents upon which the Government relies, without revealing to the jury that the investigation took place in the context of the death of a racehorse.

Accordingly, we submit that if the Court allows some evidence regarding the Delaware investigation, it should be limited to a version of the Complaint redacted to eliminate reference both to the death of the racehorse and to the allegation that the defendant failed to establish VCPR with this animal. Rather than permitting the Government to play the audio recording of the full interview, the Government should be limited to introducing a transcript of the interview with Dr. Fishman redacted to include only those portions of the questions which are not, themselves, accusatory in nature, and the defendant's answers.

Finally, because statements offered by Ms. Giannelli are not admissible against Dr. Fishman as admissions; and, vice versa, the Court should be prepared to issue an instruction regarding the use that can be made of these statements during a joint trial.

III. The Court Should Preclude The Introduction Of Evidence Obtained Pursuant To A Proffer Agreement With The Defendant Unless And Until The Government Demonstrates That The Agreement No Longer Applies

In *United States v. Barrow*, 400 F.3d 109 (2d Cir. 2005), the Court of Appeals dealt with the issue of conduct by defense counsel that may "open the door" to the introduction of statements by a defendant previously protected by a proffer agreement. The Court began its discussion with an analysis of Fed.R.Evid. Rule 410. That rule states, in pertinent part:

Except as otherwise provided in this Rule, evidence of the following is not, in any civil or criminal proceeding, admissible against the defendant who made the plea or was a participant in the plea discussions: (1) a plea of guilty which was later withdrawn; (2) a plea of *nolo contendere*; (3) any statement made in the course of any proceedings under Rule 11 of the Federal Rules of Criminal Procedure or comparable state procedure regarding either of the foregoing pleas; or (4) any statement made in the course of plea discussions with an attorney for the

prosecuting authority which do not result in a plea of guilty or which result in a plea guilty later withdrawn.

Rule 11 of the Federal Rules of Criminal Procedure includes the following:

11(f) Admissibility or Inadmissibility of a Plea, Plea Discussions, and Related Statements

The admissibility or inadmissibility of a plea, plea discussion, and any related statement is governed by Fed.R.Evid. Rule 410.

In seeking to determine whether or not arguments by counsel or conduct by the defendant triggered a waiver of the protections of the proffer agreement, the Court stated:

The mere fact that a defendant pleads not guilty and stands trial is not a factual assertion that triggers the proffer agreement waiver [...] nor are defense arguments that attempt to demonstrate why the facts put in evidence by the prosecution are insufficient to permit the jury to find the elements of the crime proved. Thus, a defense argument that simply challenged the sufficiency of the Government's proof on elements such as knowledge, intent, identity, etc., would not trigger the waiver here at issue.

Barrow at 118-119.

Moreover, the Court noted that even when it is satisfied that a factual assertion triggering a Rule 410 waiver has been made, that conclusion does not mandate receipt of the proffer statements in evidence. A waiver agreement between the parties does not divest the district court of its considerable discretion to exclude relevant evidence that may inject "unfair prejudice" or "confusion" into the jury resolution of the issues in dispute. Fed.R.Evid. Rule 403. *Id.* at 119.

We submit that, to date, the Government has failed to demonstrate that the defendant or his attorney has engaged in conduct that triggers the waiver provisions of either of the proffer agreements.

Barring such a waiver, the proffer statements are inadmissible.

IV. The Court Should Preclude The Introduction Of Evidence Regarding Dr. Fishman's Distribution Of Products Abroad (Gov't MIL XI)

In the defense Motions *in limine*, it seeks to preclude the introduction of the defendant's foreign sales of his products. The motion to preclude was made in response to the Government's 404(b) Notice, and its reference to certain conduct by an agent of the defendant's customers in the United Arab Emirates ("UAE"). At the core of the argument is the assertion that such evidence is inadmissible under the four part test set forth in *Huddleston v. United States*, 485 U.S. 681 (1988).

To the extent that evidence of the defendant's foreign sales are now labeled as direct evidence of the charges in this case, we would note that such evidence must still meet the balancing test outlined in Fed.R.Evid. Rule 403. In this regard, the Court should note our contention that the defendant's foreign sales are subject to the export exemption to the statutes prohibiting adulteration and misbranding; and, the disparate regulatory regimes of those countries to which the product is exported. *See* FDCA § 801, 21 U.S.C. § 381(e).

Since the filing of the *in limine* motions, the Court has received submissions and heard argument on the issue of the defendant's bail. These pleadings should serve as a demonstration of the likelihood that evidence of foreign sales will confuse the jury and distract them from the relevant evidence by prompting a mini trial on the issue of whether or not Dr. Fishman conformed his conduct to the export exemption to the adulteration and misbranding statutes.

We rely upon both our original motion *in limine* and our submissions in connection with the Court's review of the defendant's bail conditions to support the contention that this evidence should be precluded.

Finally, should the Court allow the introduction of such evidence, we would reserve the right to call as an expert witness, the defendant's retained expert, Ted Sullivan, Esq. or another witness with comparable qualifications, to offer testimony explaining the complex interplay between the adulteration and misbranding statutes, and the export exemption found in FDCA §801 and 21 U.S.C. § 381(e).

V. The Court Should Limit Evidence To Be Offered By The Government's Expert Witnesses (Gov't MIL XII)

In our motion, we have sought to limit duplicative evidence by the three witnesses from whom the Government seeks to elicit expert testimony. We reiterate here our request that the Court, consistent with Fed.R.Evid. Rule 702, limit the scope of testimony by the Government's expert witnesses in three respects: First, the Rule requires that the opinion testimony be the product of "scientific, technical, or other specialized knowledge." Second, the testimony must assist the "trier-of-fact to understand the evidence or to determine a fact in issue." And, third, expert testimony which does not relate to any issue in the case is not relevant and *ergo* is not helpful. *See Daubert v. Merrell Dow Pharmaceuticals Inc.*, 509 U.S. 579, 113 S.Ct. 2786 (1993).

In light of these concerns, we request that the witness be precluded from offering opinion testimony (1) defining or explaining the elements of the adulteration and misbranding statute; (2) suggesting that the purpose of the statutory scheme is to ensure the wellbeing and safety of the racehorses; or (3) that Dr. Fishman's products do not meet FDA standards of "safety and efficacy."

VI. The Court Should Permit The Defense To Call Its Expert As A Rebuttal Witness (Gov't MIL XII)

In its Expert Witness Notice, the defense proposed calling Clara Fenger, DVM to offer opinion testimony in the following areas: (1) the “clinical pharmacology” of Seth Fishman’s drugs; (2) the safety and efficacy of these products when administered to racehorses; (3) the propriety of using these product for the purpose of maintaining the health and welfare of horses involved in racing; and (4) the appropriate standards for the practice of veterinary medicine including the maintenance and treatment of herd animals such as a stable of horses.

It is ironic that the Government has objected to this offer of expert testimony, given that two of the three witnesses, from whom the Government will seek to elicit opinion testimony, were not even treated as experts in the Government’s disclosure.

The Government failed to provide even a cursory description of the subjects upon which it would seek to obtain opinion testimony from Dr. Cynthia Cole; instead, referring to materials previously provided to counsel as 3500 material. And, it suggested that Dr. Diana Link would not be offering expert opinion evidence, claiming that she was mentioned in the Government’s Expert Notice only out of “an abundance of caution.” *See* Government’s Expert Witness Notice, Defendants’ Motions *in limine* at pp. 12-13.

At the outset, it should be understood that, particularly in light of the defendant’s concerns about triggering a waiver of the protections accorded his proffer statements, it is difficult to determine whether we will present a factual defense; let alone, whether we will call an expert witness in support of that defense.

To add to the defendant’s level of uncertainty, Dr. Fenger was placed on the defendant’s witness list in order that, should the Government’s expert witnesses be permitted to offer opinion

evidence regarding the defendant's alleged violation of the adulteration and misbranding statutes, the purposes of the statutory regime; and/or the safety and efficacy of the defendant's products, the defendant would have some meaningful method for responding. We have argued in our *in limine* motion that such evidence is inadmissible. However, should the Court disagree with our assertion, and conclude that these categories of evidence are appropriate for opinion testimony by a qualified expert, we may seek to call Dr. Fenger to rebut the testimony of these individuals.

Annexed hereto as **Exhibit A** is Dr. Fenger's curriculum vitae. Should this Court permit evidence in the form of opinion testimony by the Government's experts on the areas we seek to preclude, we would offer Dr. Fenger's testimony in rebuttal, and would be prepared to provide the requisite notice required by Rule 16(g).

VII. The Court Should Permit Cross Examination Of The Government's Witnesses On All Matters That May Affect Their Credibility (Gov't MIL V and XIII)

The Government seeks to limit cross examination of both agents of law enforcement and cooperating witnesses in a fashion that may deny the defendant his Sixth Amendment right of confrontation. In the event that the Government uses the testimony of these witnesses to offer the statements of others pursuant to Fed.R.Evid. Rule 801(d)(2)(A), (C) or (E), the provisions of Fed.R.Evid. Rule 806 apply. Fed.R.Evid. Rule 806 provides as follows:

When a hearsay statement – or a statement described in Rule 801(d)(2)(C),(D) or (E) – has been admitted in evidence the declarant's credibility may be attacked and then supported by any evidence that would be admissible for those purposes if the declarant had testified as a witness.

Moreover, when an agent or cooperating witness testifies as to matters of direct knowledge, he may be cross examined in such a manner as to demonstrate bias, failure of memory, or other behavior demonstrating a lack of credibility.

The defendant reserves his right to conduct a full cross examination on these issues.

CONCLUSION

For all the foregoing reasons, we respectfully submit that the Government's motions *in limine* be denied or modified in accordance with the arguments contained herein.

Dated: New York, New York
December 15, 2021

Respectfully submitted,

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